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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,833	11/20/2002	Anil B. Mukherjee	4239-61375	8664

24197 7590 07/12/2004

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,833	MUKHERJEE ET AL.	
	Examiner	Art Unit	
	David A Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-109* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-109 are pending.

This application contains the following inventions or groups of inventions, which are not so linked as to form an inventive concept under PCT Rule 13.1.

Group I, claim(s) claims 1-5, drawn to a pharmaceutical composition for inhibiting PLA 2.

Group II, claim(s) 6-10, drawn to a pharmaceutical composition for binding fibronectin.

Group III, claim(s) 11-12, drawn to a pharmaceutical admixture.

Group IV, claim(s) 13-25, drawn to a method of inhibiting PLA_2 in vivo.

Group V, claim(s) 26-40, 65 and 106-109, drawn to a method of treating an inflammatory condition.

Group VI, claim(s) 41-53, and 66, drawn to a method of treating a fibrotic condition.

Group VII, claim(s) 54-64, and 67, drawn to a method of treating a uteroglobin deficiency.

Group VIII, claim(s) 68-72, drawn to a cosmetic composition.

Group IX, claim(s) 73-77, drawn to a cosmetic composition for binding fibronectin.

Group X, claim(s) 78-82, drawn to a blood supplement for inhibiting PLA_2.

Group XI, claim(s) 83-87, drawn to a blood supplement for binding fibronectin.

Group XII, claim(s) 88-92, drawn to an assay for quantitating uteroglobin.

Group XIII, claim(s) 93-105, drawn to a method of treating fibrillogenesis.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: with respect to unity of invention PCT Rule 13.1 states:

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Additionally, PCT Rule 13.2 states:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

With regard to the application of PCT Rule 13.37 CFR § 1.475 concerning unity of invention states:

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed the first invention of the categories related mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 37 C.F.R. § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Groups I-XIII recite a plurality of pharmaceutical compositions and/or methods each having a different intended use. The single inventive concept joining these disparate intended uses appears to be that the pharmaceutical compositions comprise and the methods use recombinant human uteroglobin. In order for the inventions of

groups I –XIII to have unity of invention it is necessary that the single inventive concept be a contribution to the prior art. However, LEYTON et al. (Cancer Research 54:3696 3699, July 15, 1994) teach recombinant human uteroglobin, teach that 1 uM recombinant human uteroglobin inhibits arachidonic acid release, and suggest recombinant human uteroglobin inhibits tumor cell invasiveness through inhibition of PLA_2-mediated arachidonic acid release. A pharmaceutical composition comprising a PLA_2 inhibiting effective amount of recombinant human uteroglobin would have been obvious to one of ordinary skill in the art. Therefore, the inventions of groups 1-XIII do not fulfill the requirements for unity of invention with respect to a contribution which each of the inventions makes over the prior art. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

The office further notes that even if the above analysis of the Groupings were not proper, there would still be a proper division of the grouping from claims 11-109. Note that claims 1 and 6 require a recombinant UG, while the UG used in the compositions or methods of claim 11 and following independent claims can be native or recombinant UG, it is thus not clear what applicant's inventive contribution over the prior art might be: the production of recombination UG, or the recognition of various inhibiting or binding activities of UG?

Should Group III be elected, election of species is required as follows;

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

The specific active agents recited in claims 65-67. Through these claims do not depend from the claims of Group III, it appears that these are a listing of what can be the "active agent" of claim 11.

The claims are deemed to correspond to the species listed above in the following manner:

No claim is limited to a particular species.

The following claim(s) are generic: each of claims 11-12 is generic to a plurality of active agents.

Should Group IV be elected, election of species is required as follows:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

The specific diseases/conditions recited in claims 23-24.

The claims are deemed to correspond to the species listed above in the following manner:

No claim is limited to a particular species.

The following claim(s) are generic: each of claims 13-25 is generic to two or more species of diseases/conditions.

Should Group V be elected, election, of species is required as follows:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

The specific diseases/conditions recited in claims 36-37, 39-40 and 106-109.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 36-37, 106 and 108-109 are each drawn to a particular species.

The following claim(s) are generic: each of claims 26-35, 38-40, 65 and 107 is generic to two or more species of diseases/conditions.

Should Group VII be elected election of species is required as follows.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

The species conditions recited in claim 64.

The claims are deemed to correspond to the species listed above in the following manner:

No claim is limited to a particular species.

The following claim(s) are generic: each of claims 54-64 and 67 is generic to a plurality of species of conditions.

Should any of Groups V-VII be elected, the following election of species is required (in addition to those stated supra for Groups V and VII).

The claims are deemed to correspond to the species listed above in the following manner:

No claim is limited to a particular species.

The following claim(s) are generic: each claim of Groups V-VIII is generic to a plurality of species of active agents.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday thru Thursday from 8 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
July 6, 2004

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644